UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

EGON LEWKUT,	§	
	§	
Plaintiff,	§	
	§	
v.	§	**CIVIL ACTION NO. 09-cv-3695**
	§	
STRYKER CORPORATION, et. al,	§	
	§	
Defendants.	§	

MEMORANDUM AND ORDER

Pending before the Court is the Motion to Dismiss of Defendant Howmedica Osteonics Corp. ("Defendant") (Doc. No. 8). After considering the parties' filings, all responses and replies thereto, and the applicable law, the Court finds that Defendant's motion should be granted.

I. FACTUAL BACKGROUND

A. Facts of this Case

Plaintiff Egon Lewkut ("Plaintiff") received an artificial hip replacement system manufactured by Defendant on or about November 15, 2006 in Ann Arbor, Michigan. (Pl. First Am. Compl., Doc. No. 5, ¶ 2.) This replacement system, called a Howmedica Osteonics Trident System ("Trident System"), consisted of several components, including an Osteonics Trident PSL Acetabular Shell ("acetabular shell" or "acetabular cup"). (*Id*.) Shortly after the surgery, Plaintiff experienced pain in his thigh, groin, and hip, which persisted for some time. (*Id*. ¶¶ 3-4.) In January 2007, Plaintiff received a bone scan, as a result of which the doctor advised him that his pain was caused by a failure in his hip prosthesis. (*Id*. ¶ 5.) The doctor also advised that Plaintiff would need

revision surgery. (*Id*.) Plaintiff was required to take pain medication for the constant pain he suffered as a result of the loose and defective hip implant. (*Id*. ¶ 7.) Plaintiff maintains that his groin pain was due to loosening of the acetabular shell component of his hip prosthesis, caused by residues that remained on the shell after manufacturing and packaging. (*Id*. ¶ 6.)

B. History of the Device

When Congress passed the Medical Devices Amendments of 1976 ("MDA"), it established "various levels of oversight for medical devices, depending on the risks they present." *Riegel v. Medtronic*, 552 U.S. 312, 316 (2008). The MDA categorizes medical devices into three classes. Of these, Class III devices receive the most federal oversight because they present the highest risks and are primarily used for "supporting or sustaining life." *Id*. at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). The United States Food and Drug Administration ("FDA") has two different processes by which they approve of Class III medical devices such as the hip replacement system that Plaintiff received. Most devices are approved based on applications urging "substantial similarity" to other already approved devices, known as the "§ 510(k) process." (Pl. Resp., Doc. No. 13-1, at 2.) Alternatively, these devices can be approved through a more rigorous premarket approval ("PMA") process, which requires manufacturers to submit extensive information to obtain approval, including clinical trials, design specifications, manufacturing processes, and quality controls. (*Id*.) After initial FDA approval, these devices are subject to continuing reporting requirements, and the FDA retains the authority to withdraw approval based on new information. (Def. Mot. at 7.)

It is undisputed that the acetabular shell received § 510(k) approval and was commercially available well before Plaintiff received his hip replacement. Subsequently, the "Trident System" received PMA approval on or about February 3, 2003. (Def. Mot Ex. A, Doc. No. 9-2.) Determining the components of the Trident System is at the heart of the parties' dispute in this case. Defendant maintains that the Trident System is comprised of four parts, including the acetabular shell. (Def. Mot. at 4.) Plaintiff, on the other hand, maintains that the Trident System, as approved by the PMA process, is comprised of only two components, or the "ceramic-on-ceramic weight bearing components." (Pl. Resp. at 2.) Thus, according to Plaintiff, the acetabular shell received FDA-approval only through the § 501(k) process.

In January 2008, Defendant initiated a recall of certain acetabular shells that were manufactured in its Cork, Ireland facilities between January 2000 and December 2007. (Pl. Resp. at 5.) According to Plaintiff, this included the specific hip device that Plaintiff originally received. Plaintiff maintains that "[t]his recall came after an investigation into deviations between specifications and processes for manufacturing required by the FDA and those found in [Defendant's] facility." (*Id.*) Among other problems, manufacturing residuals in excess of those permitted by the FDA were found on these Trident devices. According to Plaintiff, residues coating the back of the acetabular shell prevented it from being securely held into the hip socket. (*Id.*)

Plaintiff now brings this action against Defendant, alleging manufacturing, design, and marketing defects in the acetabular shell. Plaintiff asserts claims for relief under strict liability, negligence, and the Texas Deceptive Trade Practices Act ("DTPA"). He seeks actual and punitive damages. Defendant now moves to dismiss this action

pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that Plaintiff has failed to state a claim upon which relief can be granted because his claims are all preempted.

II. LEGAL STANDARD

A. Rule 12(b)(6) Motion to Dismiss

A court may dismiss a complaint for "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, a court must "accept the complaint's well-pleaded facts as true and view them in the light most favorable to the plaintiff." *Johnson v. Johnson*, 385 F.3d 503, 529 (5th Cir. 2004). "To survive a Rule 12(b)(6) motion to dismiss, a complaint 'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief—including factual allegations that when assumed to be true 'raise a right to relief above the speculative level.'" *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). That is, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. ---, 129 S.Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 570).

In considering a motion to dismiss for failure to state a claim, a district court can consider the contents of the pleadings, including attachments thereto, as well as documents attached to the motion, if they are referenced in the plaintiff's complaint and are central to the claims. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 499 (5th Cir. 2000). Furthermore, a Court may refer to matters of public record when deciding a motion to dismiss. *Chauhan v. Formosa Plastics Corp.*, 212 F.3d 595, 595 (5th Cir. 2000). Because the PMA approval and FDA documents describing the Trident System

are matters of public record, and are attached to the parties' briefs as central to this dispute, the Court will consider them in ruling upon this Motion.[1]

B. Preemption

The MDA provides that no state may impose any requirement with respect to a medical device that is "different from, or in addition to, any requirement applicable under this chapter to the device." 21 U.S.C. § 360(k)(a)(1) (2007). In the recent case of *Riegel v. Medtronic, Inc.*, the Supreme Court clarified how this preemption provision is to be applied. First, a court must determine whether the FDA has imposed safety-related requirements on the device in question. *Id*. at 322-23. The *Riegel* Court held that the PMA approval process does impose certain federal "requirements" upon the subject medical devices, because "the FDA may grant premarket approval only after it determines that a device offers reasonable assurance of safety and effectiveness." *Id*. at 323. Thus, for all PMA-approved devices, this first prong it met. By contrast, devices approved through the less rigorous § 510(k) process have not undergone review for safety or efficacy under the MDA, because the focus of that process is on equivalence, not safety. *Id*. at 323-24. Devices approved through this process, therefore, cannot necessarily be said to have met federal safety requirements.

[1] Plaintiff argues in his brief that Defendant's Motion should be treated as a Motion for Summary Judgment, which would entitle Plaintiff to discovery before the Court issued its final ruling. (Pl. Resp., Doc. No. 13-1, at 16.) Plaintiff argues that Defendant references and attaches several documents outside of the pleadings, which effectively converts its Motion into one for summary judgment. Federal Rule of Civil Procedure provides: "[i]f, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." However, as discussed above, it is also well-established that a Court may consider documents outside of the pleadings on a motion to dismiss when these documents are matters of public record. *Chauhan v. Formosa Plastics Corp*., 212 F.3d 595, 595 (5th Cir. 2000). Defendant points out that, in its briefs, it references only FDA's public records that are available on its website. Plaintiff does not dispute that Defendant includes and refers to only public documents. As such, this Court may properly treat this Motion as a motion to dismiss and consider these documents in deciding whether, as a matter of law, Plaintiff's claims should be dismissed under Federal Rule of Civil Procedure 12(b)(6).

Second, for those products that undergo the PMA process, the Court held that it must be determined whether the state claims for relief brought by a plaintiff impose safety or effectiveness requirements that are "different from, or in addition to" the FDA's requirements. *Id*. As Defendant points out, the Court concluded that state tort claims for negligence and strict liability meet the second part of this test, because these claims impose requirements additional to those that are federally imposed through the PMA process. *Id*. 323-27. However, the Supreme Court noted that "parallel" state claims, or those that simply provide for additional remedies for violations of federal requirements, were not preempted by Section 360(k). *Id*. at 330 (noting that Section 360(k) "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations").

Defendant points out in its Motion that seven courts have applied *Riegel* to hold that the MDA broadly preempts state tort claims against the Trident System. Plaintiff does not dispute the fact that the Trident System, to the extent that it was PMA-approved, would meet the first prong of the *Riegel* test. Rather, Plaintiff argues that the acetabular shell, which is the device at issue here, was not in fact part of the "Trident System" that was approved via the PMA process, and is therefore FDA-approved only via the less-rigorous § 510(k) process. Whether the acetabular shell did in fact receive PMA approval, or was approved only through the § 510(k) process, is of dispositive significance under the *Riegel* preemption analysis. Accordingly, this Court is primarily tasked with determining the legal scope of the PMA-approved device, that is, whether, based on the public records attached to the parties' briefs, the acetabular shell was indeed part of the "Trident System" approved via PMA.

III. *RIEGEL* STEP 1: COMPONENTS OF THE TRIDENT SYSTEM

This Court must first evaluate whether the acetabular shell was part of the Trident System that was indisputably PMA approved. First, the approval letter itself states that the Trident System is used for patients requiring "totally hip arthroplasty," which at least suggests that it consists of all components necessary for total hip replacement. (Def. Mot. Ex. A, B.) Second, the Draft Package Insert for the Trident System explicitly states that the PMA-approval encompasses a Trident System which "consists of a titanium alloy acetabular shell and the choice of any Trident acetabular bearing insert." (Def. Mot. Ex. D.)

Defendant points out that, on the FDA website, the description of the Trident System also states that it is a "total hip replacement system". (Def. Mot. Ex. F.) The site goes on to describe how exactly the Trident System works, stating that "[t]he cup-shaped part of the joint, called the acetabular cup, is implanted into the cup-shaped space on the outer part of the hip." (*Id.*) Thus, it seems that the description of the device anticipates the acetabular cup as part of the overall system.

Furthermore, in the Summary of Safety and Effectiveness Data performed and issued by the FDA, the Trident System is described as a ceramic-on-ceramic acetabular bearing couple with a pre-assembled titanium alloy sleeve which "mates with the metal acetabular shell *component*" (emphasis added). (*Id*. Ex. G.) That the acetabular cup is described as a "component" of the approved system is, to this Court, of considerable significance. As Defendant points out, this summary also reveals that the acetabular shell was subject to rigorous testing by the FDA, along with the other components of the Trident System. (*Id*.) Finally, several supplements approved by the FDA through the

PMA process after the Trident System's initial approval refer to the acetabular shell component in a manner that strongly suggests that it had already been approved. (Def. Mot. Ex. C (approving the trident "t" shell, a line extension to "the trident acetabular shells previously approved for use with the trident alumina insert").)

Plaintiff, however, points to the FDA July 20, 2000 public hearing, which discussed the Trident System, to support its contention that only ceramic components of the hip replacement device were approved through the PMA process. At this hearing, it appears that one employee of Defendant emphasized, in distinguishing the Trident System from another system undergoing the same process, that "only the ceramic inserts are under investigation in these systems." (Pl. Resp. Ex. F, at 12.) However, later in the meeting, it was clarified that the panel would in fact be "voting on an entire system, and not just the ceramic on ceramic interface." (*Id*. at 16.) Thus, the public hearing actually seems to support Defendant's contention that the device that was approved by the panel votes was the entire system, including the acetabular shell, and not only the ceramic components.

Plaintiff also argues that Defendant's refusal to produce the original PMA application for the Trident System, which demonstrates exactly what Trident components Defendant submitted to the FDA for approval, substantiates Plaintiff's contention that only the ceramic components of the Trident System were PMA-approved. However, this argument misses the mark. In determining the legal scope of the FDA approval of the Trident System, this Court is tasked only with determining what was ultimately approved via the PMA process. What was submitted in the FDA application has little bearing on this Court's assessment of what was ultimately approved. Indeed, whether a particular

product, whether medical device or not, is FDA-sanctioned is demonstrated to the public and recognized by the representations made by the FDA itself, not by the application documents submitted to it for review. Once the FDA chooses to undergo PMA review of a particular device, it is incumbent upon it to make clear the scope and contours of its ultimate decision. According, the Court may appropriately rely solely on the public documents released by the FDA in determining what Trident System components were approved. [2]

Weighing all of these public records, the Court concludes that the "Trident System" that was indisputably approved through the PMA process includes the acetabular shell that is the subject of this suit. Moreover, that the acetabular shell was previously approved through the less rigorous § 510(k) process does not affect this conclusion. Prior to the PMA approval of then entire Trident System, it is clear that the acetabular shell would not have satisfied the first prong of *Riegel*. Plaintiff argues in his brief that "although the metal Trident acetabular cup was approved for use with the ceramic-on-ceramic bearing components, no court has held that the mere coupling of a § 510(k) device with a PMA device somehow exempts the § 510(k) device" from state law claims. (Pl. Resp. at 12.) Thus, according to Plaintiff, although the entire "Trident System," which includes the use of an acetabular shell, was PMA-approved, each

[2] Plaintiff cites to *Kavalir v. Medtronic*, 2008 WL 4087950 (N.D. Ill. Aug. 27, 2008) to support his argument that FDA web pages are insufficient to demonstrate that *Riegel* preemption requirements are satisfied. However, the public documents examined in that case were insufficient for reasons not at issue here. There, the court noted that none of the pages attached to the defendant's brief identified the components of the medical device that were named in the plaintiff's complaint. *Id.* at *4. The court, therefore, concluded that the pages did not sufficiently demonstrate that the components named in the complaint had received premarket approval. *Id.* Here, by contrast, the acetabular shell at issue is specifically identified in the FDA documents as a component of the Trident System that was PMA-approved. Accordingly, the Court can appropriately base its conclusion on these public documents.

individual component must undergo the PMA process in order for *Reigel* preemption analysis to apply.

However, several courts have now explicitly or implicitly reached the conclusion that, when the Trident System was approved in 2003, all of its components were deemed to have undergone the PMA process. *See Lemelle v. Stryker Orthopaedics*, --- F. Supp. 2d ---, 2010 WL 996523 (W.D. La. March 15, 2010) (dismissing state law product liability claims against the Trident System, including those involving acetabular shells); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *4 (D.N.J. March 5, 2009) (noting that additional discovery was not warranted because defendant had sufficiently demonstrated that the entire Trident System underwent the PMA process); *Funk v. Stryker Corp*., 673 F. Supp. 2d 522 (S.D. Tex. 2009) (treating the Trident System as a single device and concluding that it was approved under the PMA process); *Bausch v. Stryker Corp.*, 2008 WL 5157940, at * 3 (N.D. Ill. Dec. 9, 2008) (noting that Trident, including the acetabular shell, was subjected to the process of pre-market approval and therefore subject to federal regulations).

Indeed, courts have also found, in the context of other medical devices, that attempting to separate the component parts of a medical device for purposes of preemption is not appropriate. *See Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (noting that various components of a PMA-approved device worked together as a single medical device, and that picking these components apart to apply different preemption analysis "makes no sense"). Similarly, this Court cannot see the logic in holding that the ceramic components of the Trident System were PMA-approved for use with the acetabular shell, but that that acetabular shell itself was not PMA

approved. An acetabular shell being used in conjunction with the identified ceramic components is precisely the device that was approved via PMA. To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers.

Thus, that the acetabular shell was previously approved through only the § 510(k) process, and was commercially available when the Trident System was approved, does not change the fact that it was later subject to the more rigorous scrutiny of the PMA process as a component of the Trident System. Because the Trident System went through the PMA process, and the acetabular shell was part of this system, the first part of the *Riegel* test is satisfied. Therefore, the shell was subject to federal government regulations for purposes of preemption, and the Court must determine whether Plaintiff's state law claims impose requirements that are different from, or in addition, to, these requirements.

IV. *RIEGEL* STEP 2: ADDITIONAL STATE LAW REQUIREMENTS

In holding that state law claims are preempted if they impose requirements additional to those that are federally mandated, *Riegel* nonetheless explicitly leaves open the possibility of parallel state claims, even for those devices that are approved through the PMA process. Thus, this Court must determine whether the state law claims asserted by Plaintiff constitute legal duties that are different from, as opposed to parallel to, the federal requirement implicated through the PMA process.

A. Preemption of State Claims Generally

In this case, Plaintiff brings claims against Defendant for strict liability, negligence, and the DTPA. These causes of action are premised on alleged manufacturing, marketing, and design defects in the acetabular shell. In *Riegel* itself, the Court concluded that the MDA's preemption provision preempted products liability claims, including claims for negligence and strict liability, brought in the context of PMA-approved medical devices. *Riegel*, 552 U.S. at 324. Moreover, with respect to alleged manufacturing defects in particular, it was noted in *Riegel* that the MDA forbids the manufacturer to make changes in manufacturing processes that would affect safety or effectiveness, and that any such changes are subject to FDA approval under "largely the same criteria as the initial application." *Id.* at 319. Therefore, any changes or failures in the manufacture of the Trident System would be subject to this federal law.

Furthermore, the Texas Supreme Court has, even prior to *Riegel*, held that DTPA claims against PMA devices may be preempted. *Worthy v. Collagen Corporation*, 967 S.W.2d 360, 376-377 (Tex. 1998) (noting that the FDA premarket approval of Zyderm, as opposed to the PMA process in general, is sufficiently specific to have a preemptive effect on plaintiff's DTPA claim). Although *Worthy* did not hold that the PMA process necessarily preempts any state claim brought under DTPA, courts in this district have cited to it in concluding that DTPA state claims are preempted in the context of the Trident System. *Funk v. Stryker*, 673 F. Supp. 2d 522, 531 (S.D. Tex. 2009) (noting that any doubts as to whether DTPA claims can survive preemption are dispelled by *Worthy*). Moreover, as Defendant points out, the underlying basis for Plaintiff's DTPA claims in this case are conclusively preempted. Plaintiff bases his DTPA claim on a breach of the implied warranty of merchantability, failure to disclose, and false representations.

However, *Riegel* addressed these very allegations, noting that the PMA process necessarily involves a determination that the FDA-approved label for the subject medical device is neither "false not misleading," and that state common law requirements for additional warnings are preempted. *Id*. at 318, 329.

Indeed, it has been observed by one court that "in the ten months following *Riegel*, courts across the country have applied Section 360(k) broadly, preempting all manner of claims from strict products liability and negligence . . . to failure to warn and manufacturing-and-design defect." *Lemelle*, 2010 WL 996523, at *13 (noting that state law product liability claims are preempted by the MDA); *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (collecting cases); *see also Funk*, 673 F. Supp. 2d at 531 (dismissing claims for strict liability, negligence, and violations of the DTPA); *Delaney*, 2009 WL 564243, at *2-*7 (concluding that Plaintiff's claims for failure to warn, defective manufacture, defective design, negligence and recklessness, breach of warranties, and fraud were preempted because they imposed different or additional requirements upon the Trident System); *Horowitz v. Stryker*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (holding that plaintiff's negligence, defective manufacturing, defective design, breach of warranty, and failure to warn claims were preempted by the MDA and FDCA (defined below)); *but see Hofts v. Howmedica Osteonics Corp*., 597 F. Supp. 2d 830, 839-40 (S.D. Ind. 2009) (holding that plaintiff's state claims were not preempted because defendant failed to show that these claims rested on standards other than those permitted by the FDA). In accordance with the high degree of consensus apparent in this case law, this Court must, therefore, recognize that Plaintiff's state law claims of negligence, strict products liability, and

DTPA do impose additional safety requirements such that they would be preempted under *Riegel* by the federal requirements inherent in the PMA process.[3]

B. Preemption of Claims of Adulterated Devices

Plaintiff argues however, that his pleadings invoke parallel, rather than distinct, state law requirements. Plaintiff points out that under *Riegel*, the MDA does not prevent a State from providing a damages remedy for claims based upon violations of the FDA requirements. (Pl. Resp. at 14.) Plaintiff avers in his Complaint that the Trident System he recieved was "adulterated" under Section 351(h) of the Food, Drug, Cosmetic Act ("FDCA"). 21 U.S.C. § 351(h) (1997). Section 351(h) of Title 21 states that Class III medical devices are adulterated only if "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with" applicable requirements or conditions. According to Plaintiff, as demonstrated by the recall of certain acetabular shells that were manufactured in Ireland in 2008, Defendant violated federal regulations and requirements, including "making an adulterated device that proximately caused Plaintiff's injuries and damages." (Pl. First. Am. Compl. ¶ 23.) More specifically, Plaintiff's Complaint alleges that the "Trident acetabular cup contained manufacturing defects in that it was adulterated as a result of being manufactured in violation of FDA regulations and requirements." (*Id.*, at 10-11.)

1. *Riegel* Preemption

According to Plaintiff, because he unequivocally pleads that the Trident System was adulterated—that is, violated federal safety regulations—state laws can provide a remedy for such alleged violations without running afoul of preemption. Even prior to

[3] Because the reasoning in *Hofts* has been discredited by several other courts, this Court declines to adopt the analysis of that case.

Riegel, the Supreme Court recognized that Section 360(k) does not preclude states from providing "a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). "The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute, rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id*.

Plaintiff is correct that *Riegel* did nothing to disturb this prior holding. Thus, this Court recognizes that, under *Reigel*'s specific holding that Section 360(k) does not prohibit States from providing a damages remedy for claims premised on FDA violations, common law state actions that provide private remedies for violations of FDCA provisions would be permissible. *Riegel*, 553 U.S. at 330; *see Mitchell v. Collagen Corp.*, 126 F.3d 902, 907 (7th Cir. 1997) (noting that to the extent that plaintiff's adulteration claim alleged that defendant had not followed FDA requirements, state law did not impose requirements different from, or in addition to, the federal requirements).

2. Preemption under 21 U.S.C § 337(a)

Nonetheless, the statutory language of the FDCA, as well as case law, makes clear that the provisions of the FDCA, including that which establishes and defines the prohibition on "adulterated devices", are to be enforced through the United States government only. 21 U.S.C. § 337(a) (providing that "all proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"). Accordingly, courts have held that that private enforcement of FDCA regulations via state common law would interfere with this regulatory scheme and is

therefore prohibited. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001) (holding that the federal government, and not private litigants, are authorized to bring actions under FDCA because "[a]s a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA and the MDA"); *Medtronic*, 592 F. Supp. 2d 1147, 1161 (holding that plaintiffs cannot make an end run around the lack of a private right of action under the FDCA by recasting FDCA violations as violations of state common law); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (holding that "plaintiff cannot escape preemption by reference to provisions of the FDCA that govern the sale of adulterated and misbranded devices").

Indeed, in *Medtronic*, the court explicitly addressed the argument that holding medical device claims alleging violations of the FDCA preempted is inconsistent with *Riegel*'s holding regarding parallel state claims. The court there reasoned that alleged violations of the FDCA are not preempted because they run afoul of Section 360(k)(a), or the type of preemption addressed in *Riegel*, but rather because such claims are impliedly preempted by 21 U.S.C. § 337(a). *Medtronic*, 592 F. Supp. 2d at 1162. Moreover, with specific reference to an allegation of adulteration, the *Medtronic* court held that, because the Plaintiff's manufacturing defect claims were preempted, the "derivative assertion" that the devices in question were adulterated is also preempted, as adulteration necessarily hinged on the manufacturing process. *Id*. at 1162.

Therefore, it is clear that Plaintiff's allegations, even to the extent that they present parallel state claims and are exempt from *Riegel* preemption, are nonetheless

preempted by the federal statute that explicitly precludes private enforcement of federal laws regarding "adulterated" devices. 21 U.S.C. § 337. Thus, in accordance with the explicit terms of this statute and the relevant case law, this Court must find and hold that all of the state claims alleged by Plaintiff are preempted by the federal regulatory scheme governing medical devices such as the Trident System. Because each of the claims imposes requirements in addition to those imposed by the MDA, and because Plaintiff, as a private citizen, may not assert claims for relief on the basis of an adulterated device, this Court holds that these claims must be dismissed.

The Court recognizes and deeply regrets all that Plaintiff has suffered in this case. Were it not faced with such uniform and consistent legal precedent, this Court would have reasoned that these claims should be allowed to proceed in order to allow Plaintiff a meaningful opportunity to obtain redress for the pain he has endured.

V. CONCLUSION

For the reasons stated above, this Court holds that Defendant's Motion to Dismiss (Doc. No. 8) is hereby **GRANTED** as a matter of law. Plaintiff's case is **DISMISSED WITH PREJUDICE**. Defendant's Motion to Stay Discovery Pending Resolution of the Motion to Dismiss (Doc. No. 14) is **DISMISSED AS MOOT**. Defendant Stryker Corporation's Motion to Dismiss (Doc. No. 10) is also **DIMISSED AS MOOT**.

IT IS SO ORDERED.

SIGNED this 16th day of April, 2010.

KEITH P. ELLISON
UNITED STATES DISTRICT JUDGE